REMARKS

The following remarks are submitted as a full and complete response to the Office Action issued on August 18, 2010. Currently claims 1-16 are pending.

Claim 1 has been amended to recite that the sustained-release core comprises a mixture of the active ingredient and the polymer. Support for this amendment can be found, for example, in paragraph [0063] of the published application. Claim 1 has also been amended to recite that the formulation is a three-layer-containing tablet. Support for this amendment can be found throughout the specification, for example, in paragraphs [0015] – [0018] of the published application. Claim 16 has been amended to specify that the percentages of tamsulosin are based on the total of the tamsulosin in the sustained release formulation. Support for this amendment can be found, for example, in paragraphs [0027] and [0054] of the published application. Applicants submit that these amendments are not new matter and their entry is requested.

Reconsideration of all outstanding rejections is respectfully requested in view of the following remarks.

Rejection under 35 U.S.C. §112, first paragraph

The Patent Office has rejected claims 1-16 under 35 U.S.C. §112, first paragraph for lack of written description, specifically new matter with respect to the term "multi-layer tablet." Claim 1 has been amended to replace "multi-layer tablet" with "three-layer-containing tablet," which the Examiner had indicated was supported by the written description. Applicants submit that this amendment obviates the rejection of claims 1-16 under 35 U.S.C. §112, first paragraph. Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. §112, second paragraph

The Patent Office has rejected claim 16 under 35 U.S.C. §112, second paragraph for being indefinite, specifically concerning the basis for the percentages of tamsulosin set forth in the claims. Claim 16 has been amended to specify that the percentages of tamsulosin are based on the total of the tamsulosin in the sustained release formulation. Applicants submit that this amendment obviates the rejection of claim 16 under 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. §103(a)

The Patent Office has rejected claims 1-16 under 35 U.S.C. §103(a) as being unpatentable over Shinoda et al. (U.S. Publ. Appln. No. 2003/0147948) ("Shinoda"). The Patent Office contends that Shinoda teaches that sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicone dioxide, etc.) using a binder such as hydroxypropyl methylcellulose, wherein the particle is then further coated with a polymer substance such as an enterosoluble polymer substance, and then a polymer substance with drug may be layered onto the particles, and then the particles may be coated with an enterosoluble polymer substance. The Patent Office contends that the claimed subject matter is obvious from the teachings of Shinoda et al. Applicants respectfully disagree.

As currently amended, claim 1 recites a sustained-release formulation which is a "three-layer-containing tablet", in which a sustained-release core comprises a mixture of an active

ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions. Applicants submit that this sustained-release is not taught or suggested by Shinoda.

Specifically, sustained-release particles formulated by "layering the drug onto a core particle using a binder such as hydroxypropyl methylcellulose" is different from the claimed sustained-release core comprising a mixture of an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions, because the drug layered on the core in Shinoda is not homogeneous with the binder (such as hydroxypropyl methylcellulose) as in the claimed invention. Thus, Shinoda does not disclose or suggest this element of the claimed sustained-release formulation.

In addition, the Patent Office contends that the drug containing layer disclosed in Shinoda contains a drug and hydrophilic polymer. However, Applicants submit that Shinoda does not teach that the drug containing layer contains a hydrophilic polymer. See, for example, paragraphs [0074] and [0055] of Shinoda.

Furthermore, Shinoda teaches that the formulation in Shinoda is related to a quick-disintegrating tablet in the buccal cavity comprising sustained-release fine particles and the formulation is intended for preventing segregation of sustained-release fine particles and filler used in quick-disintegrating tablets in the buccal cavity. Additionally, Shinoda teaches that segregation of sustained-release fine particles and filler can be prevented by preparing a granulation product comprising sustained-release fine particles, several of which have aggregated together during this granulation process, using a granulation process whereby all or part of the surface of individual sustained-release fine particles is covered with filler. Thus, the sustained-release formulation recited in claim 1 of the present application is distinguished from

the formulation of Shinoda in that the claimed subject matter is directed to a sustained-release three-layer-containing tablet as a final product, and Shinoda provides a quick-disintegrating tablet in the buccal cavity.

More specifically, Shinoda teaches that "tableting" can be performed using, for instance, ... after adding the necessary additives, ... and the like, to the above-mentioned composition." (see paragraphs [0079] and [0080]). From this description, the formulation taught by Shinoda is made by mixing sustained-release fine particles with additives, and then tableting the mixture. Thus, the formulation of Shinoda is the form in which sustained-release fine particles are dispersed in additives.

In comparison with the formulation of Shinoda, the formulation recited in claim 1 of the present application is a three-layer-containing tablet comprising a sustained release core, an enteric film coating layer, and an active ingredient-containing film coating layer. Shinoda does not disclose or suggest any such sustained-release three-layer-containing tablet having the three layers specified in claim 1. Accordingly, the formulation recited in claims 1-16 of the present application is not rendered obvious by Shinoda.

In view of the above, Applicants submit that Shinoda does not render the claimed subject matter obvious. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Conclusion

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants

respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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